

## CLAIMS

I claim:

1. An instrumented prosthetic knee trial comprising:  
an articulating surface;  
5 a polymer layer at the articulating surface; and  
a body having a curved contoured surface;  
a sensor array between the polymer layer and the curved contoured surface of the  
body, the sensor array having a curved contour substantially following the curved contour  
of at least part of curved contoured surface of the body, the sensor array being capable of  
10 generating a signal in response to pressure;  
the polymer layer having a curved contour substantially following the curved  
contour of the sensor array, the polymer layer overlying substantially all of the sensor  
array.
2. The instrumented prosthetic joint trial of claim 1 including a tibial tray trial,  
15 wherein the body comprises a tibial insert trial received in the tibial tray trial, said  
polymer layer and sensor array being carried on the tibial insert trial.
3. The instrumented prosthetic joint trial of claim 1 wherein the polymer layer has a  
thickness of about 1/32 inch.

4. The instrumented prosthetic joint trial of claim 1 wherein the polymer layer comprises polyethylene.
5. The instrumented prosthetic joint trial of claim 1 wherein the curved contoured surface of the body includes two concave portions.
- 5 6. The instrumented prosthetic joint trial of claim 1 further comprising electrical leads connected to the sensor array and extending beyond the polymer layer.
7. A knee joint tension sensor device comprising a polymer layer and a sensor array secured to the polymer layer, the polymer layer and the sensor array both having a curved contour, the sensor array being capable of generating a signal in response to pressure.
- 10 8. The knee joint tension sensor device of claim 7 wherein the polymer layer comprises polyethylene.
9. The knee joint tension sensor device of claim 7 further comprising a body having a curved contoured surface, wherein the sensor array is secured to the curved contoured surface of the body, and the layer of polyethylene covers the sensor array, and wherein  
15 the sensor array and layer of polyethylene are contoured to match the contour of at least part of the curved contoured surface of the body.

10. The knee joint tension sensor device of claim 7 wherein the sensor array comprises a grid of force transducers.

11. The knee joint tension sensor device of claim 10 wherein the joint tension sensor device comprises a tibial trial.

5 12. The knee joint tension sensor device of claim 11 wherein the polymer layer has a thickness of about 1/32 inch.

13. A system for balancing soft tissue intraoperatively during knee joint arthroplasty comprising:

a first joint trial having a curved convex articulating surface;

10 a second joint trial having a curved concave articulating surface for receiving the convex articulating surface of the first joint trial;

the second joint trial including:

a polymer layer at the articulating surface;

15 a sensor array below the polymer layer, the sensor array having a curved convex contour substantially following the curved concave contour of the articulating surface, the sensor array being capable of generating a signal in response to pressure; and

a body below the sensor array, the body having a curved concave surface adjacent to the sensor array.

14. The system of claim 13 wherein the first joint trial comprises a femoral trial and the second joint trial comprises a tibial trial.

15. The system of claim 13 wherein the polymer layer has a thickness of about 1/32 inch.

5 16. The system of claim 13 wherein the polymer layer comprises polyethylene.

17. The system of claim 13 further comprising electrical signal carrying lines leading from the sensor array, at least parts of said electrical signal carrying lines being spaced from the polymer layer.

18. The system of claim 17 further comprising a computer connected to the electrical  
10 signal carrying lines.

19. The system of claim 18 further comprising a camera operatively connected to the computer.

20. A method of making an instrumented prosthetic knee trial comprising:  
providing a curved contoured forming surface;  
15 providing a conformable sensor array;

providing a polymer material;

forming the polymer material over the curved contoured forming surface so that the polymer material has a curved contoured surface that substantially mates with the curved contoured forming surface; and

- 5 assembling the formed polymer material and conformable sensor array so that the conformable sensor array is positioned against the curved contoured surface of the polymer material;

wherein the conformable sensor array conforms substantially to the curved contoured surface of the polymer material.

- 10 21. The method of claim 20 further comprising providing a prosthetic trial body having an articulating surface shaped substantially like the curved contoured forming surface, and assembling the sensor array, formed polymer material and prosthetic trial body together.

22. The method of claim 21 further comprising affixing the conformable sensor array  
15 to at least one of the formed polymer material and prosthetic trial body.

23. The method of claim 22 wherein the conformable sensor array is affixed to both the formed polymer material and the prosthetic trial body.

24. The method of claim 22 wherein affixing includes using a silicone adhesive.

25. The method of claim 23 wherein affixing includes using a silicone adhesive.
26. The method of claim 20 wherein the polymer material is provided in sheet form and forming comprises vacuum forming.
27. The method of claim 20 further comprising terminal sterilization of the assembled  
5 prosthetic joint trial by exposure to hydrogen peroxide.
28. The method of claim 20 further comprising terminal sterilization of the assembled prosthetic joint trial by exposure to gas plasma.
29. A method of balancing soft tissue during knee joint arthroplasty comprising:  
providing a first joint trial having a curved convex articular surface;  
10 providing a second joint trial having a curved concave articular surface for receiving the convex articular surface of the first joint trial;  
the second joint trial including:  
a curved concave protective layer at the articulating surface;  
a sensor array below the protective layer, the sensor array having a curved  
15 contour substantially following the curved contour of the articulating surface, the sensor array being capable of generating a signal in response to pressure; and

a body below the sensor array, the body having a curved concave surface

adjacent to the sensor array;

the method further comprising:

resecting adjacent portions of two bones;

- 5        placing the first joint trial on one of the resected bones and placing the second joint trial on the second resected bone;

flexing the bones about the first and second joint trials so that portions of the first joint trial bear against portions of the protective layer of the second joint trial.

30.    The method of claim 29 wherein the protective layer comprises polyethylene.

- 10    31.    The method of claim 29 wherein the protective layer has a thickness of about 1/32 inch.

32.    The method of claim 29 further comprising determining the contact area on one concave area of the articulating surface of the second joint trial at a plurality of relative positions of the first and second joint trials.

- 15    33.    The method of claim 29 further comprising determining the distribution of pressure on one concave area of the articulating surface of the second joint trial at a plurality of relative positions of the first and second joint trials.

34. The method of claim 29 further comprising measuring forces at the articulation between the first and second trials.

35. The method of claim 29 further comprising intraoperatively recording data selected from the group including at least one of the following: images of the surgical  
5 procedure; forces at the articulation between the first and second trials; and pressure distribution across at least a portion of the sensor array.

36. The method of claim 29 further comprising releasing soft tissue around the joint.

37. A method of instructing surgeons in the art of knee joint arthroplasty comprising:  
providing a first joint trial having a curved convex articular surface;  
10 providing an instrumented second joint trial having a curved concave articulating surface for receiving the convex articulating surface of the first joint trial;  
the second joint trial including:  
a curved concave protective layer at the articulating surface;  
a sensor array below the protective layer, the sensor array having a curved  
15 concave contour substantially following the curved concave contour of the articulating surface of the second joint trial, the sensor array being capable of generating a signal in response to pressure; and  
a body below the sensor array, the body having a curved concave surface adjacent to the sensor array;



the method further comprising:

resecting adjacent portions of two bones;

placing the first joint trial on one of the resected bones and placing the second joint trial on the second resected bone;

5           flexing the bones about the first and second joint trials so that portions of the first joint trial bear against contact portions of the protective layer.

38.       The method of claim 37 further comprising providing a computer to receive signals from the sensor array.

39.       The method of claim 38 further comprising providing an image recording  
10       device operatively connected to the computer.

40.       A system for balancing soft tissue intraoperatively during knee joint arthroplasty comprising:

a body having a curved concave surface;

a conformable sensor array; and

15       a preformed protective cover having a curved concave surface and an opposite curved convex surface.

41.       The system of claim 40 wherein the preformed protective layer is locked to the joint trial and the conformable sensor array is positioned between the curved

convex surface of the preformed protective cover and the curved concave surface of the body.

42. The system of claim 41 wherein the protective layer is adhered to the sensor array and to the body.